Division of Medical Assistance
Botulinum Toxin Treatment:
Type A (Botox)
Type B (Myobloc)

Clinical Coverage Policy No.: 1B-1
Original Effective Date: April 1, 1991
Revised Date: March 1, 2007

Table of Contents

Division of Medical Assistance	**Clinical Coverage Policy No.: 1B-1**
Botulinum Toxin Treatment:	**Original Effective Date: April 1, 1991**
Type A (Botox)	**Revised Date: March 1, 2007**
Type B (Myobloc)	

1.0 Description of the Product

Botulinum toxin type A (Botox) and botulinum toxin type B (Myobloc) injections are used for conditions in which neuromuscular blockade is indicated. They produce a presynaptic neuromuscular blockade by preventing the release of acetylcholine from the nerve endings. The resulting chemical-denervation of muscle produces local paresis or paralysis and allows individual muscles to be weakened selectively. They have the advantage of being potent neuromuscular blocking agents with good selectivity, duration of action, with the smallest antigenicity, and fewest side effects.

In clinical conditions, such as cervical dystonia, excessive and abnormal regional muscle contraction causes torsion, spasticity and pain. Botulinum toxin, injected in a focal fashion, produces neuromuscular blockade and paralysis. As symptoms abate, repeat injections may be required. Eventual loss of response to repeated injections may occur in some patients who have received botulinum toxin treatment. Immunoresistance may be one of the reasons for this development. As experience accumulates with other toxin types, similar resistance could be observable.

2.0 Eligible Recipients

2.1 General Provisions

Medicaid recipients may have service restrictions due to their eligibility category that would make them ineligible for this service.

2.2 EPSDT Special Provision: Exception to Policy Limitations for Recipients under 21 Years of Age

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid recipients under 21 years of age **if** the service is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition identified through a screening examination.** A screening examination includes any evaluation by a physician or other licensed clinician. EPSDT does not require the state Medicaid agency to provide any service, product, or procedure that is unsafe, ineffective, or experimental/investigational.

Service limitations on scope, amount, duration, and/or frequency and other specific criteria described in clinical coverage policies may be exceeded or may not apply provided documentation shows that the requested service is medically necessary to correct or ameliorate a defect, physical or mental illness, or a condition identified through a screening examination.

****EPSDT and Prior Approval Requirements:**

a. If the service, product, or procedure requires prior approval, the fact that the recipient is under 21 years of age does **NOT** eliminate the requirement for prior approval.

b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in sections 2 and 6 of the ***Basic Medicaid Billing Guide*** and on the EPSDT provider page. The Web addresses are specified below.

***Basic Medicaid Billing Guide*:** http://www.ncdhhs.gov/dma/medbillcaguide.htm

EPSDT provider page: http://www.ncdhhs.gov/dma/EPSDTprovider.htm

3.0 When the Product Is Covered

Important Note: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are medically necessary to correct or ameliorate a defect, physical and mental illness, or a condition identified through a screening examination (**subject to prior approval requirements, if applicable**). For additional information about EPSDT, see **Section 2.0** of this policy or visit the DMA Web sites specified below.

***Basic Medicaid Billing Guide*:** http://www.ncdhhs.gov/dma/medbillcaguide.htm

EPSDT provider page: http://www.ncdhhs.gov/dma/EPSDTprovider.htm

3.1 General Criteria

Medicaid covers botulinum toxins when the treatment is medically necessary, and:

a. the treatment is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs.

b. the treatment can be safely furnished, and for which no equally effective and more conservative or less costly treatment is available statewide.

c. the treatment is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker or the provider.

d. there is no contraindications to botulinum toxin injection present, including infection at the proposed injection site, and there is no hypersensitivity to any ingredient in the formulation

3.2 Coverage of Botulinum Toxin Type A (Botox)

Medicaid covers botulinum toxin type A (Botox) for the following conditions:

a. Chronic anal fissure refractory to conservative treatment

b. Esophageal achalasia patients in whom surgical treatment is not indicated

c. Blepharospasm

d. Spasmodic torticollis, secondary to cervical dystonia

e. Hereditary spastic paraplegia

f. Multiple sclerosis for patients with spasticity

g. Neuromyelitis optica for patients with spasticity secondary to spinal cord involvement
h. Other demyelinating diseases of central nervous system with secondary spasticity
i. Spastic hemiplegia and hemiparesis affecting dominant side
j. Spastic hemiplegia and hemiparesis affecting non-dominant side
k. Congenital diplegia – Infantile hemiplegia
l. Infantile cerebral palsy, specified or unspecified
m. Disorders of eye movement (strabismus) including conditions covered by ICD-9 codes 378.00 through 378.9
n. Laryngeal spasm
o. Achalasia and cardiospasm
p. Gustatory hyperhydrosis (Frey's syndrome)
q. Hemifacial spasms
r. Primary focal hyperhidrosis due to axillary hyperhidrosis

For the purposes of this policy, primary axillary hyperhidrosis is defined as a condition involving focal, visible, and severe sweating of at least a 6-month duration without apparent cause that has at least two of the following characteristics:

a. sweating is bilateral and relatively symmetric,
b. impairs daily activity,
c. episodes occur at least once per week,
d. the age of onset was less than 25 years,
e. there is a positive family history, and
f. focal sweating stops during sleep.

Treatment of severe axillary hyperhidrosis with Botox is considered as medically reasonable and necessary only for patients in whom the axillary hyperhidrosis is barely tolerable or intolerable, and frequently or always interferes with daily activities in spite of optimal treatment with topical agents, such as prescription-strength aluminum chloride, or those patients who could not tolerate these agents.

All of the following criteria must be met:

a. The patient has documented medical complications due to hyperhidrosis, (i.e., skin maceration with secondary skin infections or significant constant disruption of professional life); and
b. Documentation that the patient has failed a 6-month trial of conservative management including the use of topical aluminum chloride or extra strength antiperspirants.

3.3 Coverage of Botulinum Toxin Type B (Myobloc)

Medicaid covers botulinum toxin type B (Myobloc) for the treatment of spasmodic torticollis, secondary to cervical dystonia.

Medicaid covers botulinum toxin type B (Myobloc) for the FDA-approved treatment of patients with cervical dystonia to reduce the severity of abnormal head position and neck

pain associated with cervical dystonia. The recipient's medical record must document findings consistent with spasmodic torticollis.

Note: The choice of selecting botulinum toxin type A or B as the preferred initial agent for cervical dystonia treatment rests in the hands of the managing physician.

3.4 Electromyography

Medicaid covers electromyography when it is medically necessary to determine the proper injection site(s). See **Attachment A** for billing information.

4.0 When the Product Is Not Covered

Important Note: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are medically necessary to correct or ameliorate a defect, physical and mental illness, or a condition identified through a screening examination (**subject to prior approval requirements, if applicable**). For additional information about EPSDT, see **Section 2.0** of this policy or visit the DMA Web sites specified below.

***Basic Medicaid Billing Guide*:** http://www.ncdhhs.gov/dma/medbillcaguide.htm

EPSDT provider page: http://www.ncdhhs.gov/dma/EPSDTprovider.htm

4.1 General Criteria

Botulinum toxin treatment is not covered when:

a. the recipient does not meet the eligibility requirements listed in **Section 2.0.**
b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**.
c. the procedure in appropriately duplicates another provider's procedure.
d. the procedure is experimental, investigational,or part of a clinical trial.

4.2 Botulinum Toxin Type B (Myobloc)

Use of botulinum toxin type B for disorders other than cervical dystonia as indicated in **Section 3.3** is not covered.

4.3 Non-covered Conditions

a. Anal spasm, irritable colon, biliary dyskinesia or any treatment of other spastic conditions, including the treatment of smooth muscle spasm, not indicated in **Section 3.0** are considered to be cosmetic, investigational, not safe and effective, and are not accepted as the standard of practice within the medical community.
b. Treatment of headaches, craniofacial wrinkles, sialorrhea, and neurogenic bladder is not covered.

5.0 Policy Guidelines

Important Note: EPSDT allows a recipient less than 21 years of age to receive services in excess of the limitations or restrictions below and without meeting the specific criteria in this section when such services are medically necessary to correct or ameliorate a defect, physical and mental

illness, or a condition identified through a screening examination (**subject to prior approval requirements, if applicable**). For additional information about EPSDT, see **Section 2.0** of this policy or visit the DMA Web sites specified below.

***Basic Medicaid Billing Guide*:** http://www.ncdhhs.gov/dma/medbillcaguide.htm

EPSDT provider page: http://www.ncdhhs.gov/dma/EPSDTprovider.htm

5.1 FDA Guidelines for Administration of Botulinum Toxins

Before considering botulinum toxin treatment, it should be established that the patient has been unresponsive to conventional methods of treatments such as medication, physical therapy, and other appropriate methods used to control and/or treat spastic conditions.

The patient who has a spastic or excessive muscular contraction condition is usually started with a low dose of botulinum toxin. Other spastic or muscular contraction conditions, such as eye muscle disorders (e.g., blepharospasm) may require lesser amounts of botulinum toxin. For larger muscle groups, it is generally agreed that once a maximum dosage per site has been reached and there is no response, the treatment is discontinued. With response, the effect of the injections generally lasts for three months, at which time the patient may need repeat injections to control the spastic or excessive muscular condition. It is usually considered not medically necessary to give botulinum toxin injections for spastic or excess muscular contraction conditions more frequently than every 90 days, unless acceptable justification is documented for more frequent use in the initial therapy.

Treatments may be continued unless any two treatments in a row, utilizing an appropriate or maximum dose of botulinum toxin, failed to produce satisfactory clinical response. Providers must also document the response to these injections after every third session.

5.1.1 Dosage Limitations for Botulinum Toxin Type A (Botox)

The cumulative dosage should not exceed 600 units per 90 days.

5.1.2 Limitations for Botulinum Toxin Type B (Myobloc)

10,000 units per 12 weeks (84 days).

5.2 Unit Limitations

Medicaid covers one injection of Botox or Myobloc per site regardless of the number of injections made into the site. A site is defined as including muscles of a single contiguous body part, such as, a single limb, eyelid, face, neck, etc.

5.3 Administration Fee

Medicaid covers an administration fee when billed with the injection (J0585 or J0587) on the same day of service with the J0585 or J0587 code.

Note: An administration fee is not covered on the same day of service as an E/M code for recipients age 21 and over.

6.0 Providers Eligible to Bill for the Procedure, Product, or Service

Providers who meet Medicaid's qualifications for participation and are currently enrolled with the N.C. Medicaid program are eligible to bill for botulinum toxin treatment when the treatment is within the scope of their practice.

7.0 Additional Requirements

Documentation in the recipient's medical record should include all of the following elements:

a. Support for the medical necessity of the botulinum toxin injection
b. A covered diagnosis
c. A statement that traditional methods of treatments have been unsuccessful
d. Dosage and frequency of the injections
e. Support for the medical necessity of electromyography procedures, if used
f. Support of the clinical effectiveness of the injections
g. Specific site(s) injected

8.0 Policy Implementation/Revision Information

Effective Date: April 1, 1991

Revision Information:

Date	Section Revised	Change
03/01/2007	Throughout policy	Coverage criteria and diagnoses for botulinum toxin type A (Botox) were clarified.
03/01/2007	Throughout policy	Coverage of botulinum toxin type B (Myobloc) was implemented as a covered treatment when provided in accordance with the criteria and guidelines in the policy.

Attachment A: Claims-Related Information

Reimbursement requires compliance with all Medicaid guidelines, including obtaining appropriate referrals for recipients enrolled in the Medicaid managed care programs.

A. Claim Type

Providers bill for services using the CMS-1500 claim form.

B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

a. Botulinum Toxin Type A

333.81	Blepharospasm
333.83	Spasmodic torticollis (secondary to cervical dystonia)
334.1	Hereditary spastic paraplegia
340	Multiple sclerosis(with secondary code to indicate spasticity)
341.0	Neuromyelitis optica(with secondary code to indicate spasticity
341.8	Other demyelinating diseases of central nervous system(with secondary code to indicate spasticity
342.11	Spastic hemiplegia and hemiparesis affecting dominant side
342.12	Spastic hemiplegia and hemiparesis affecting non-dominant side
343.0 through 343.4	Congenital diplegia – Infantile hemiplegia
343.8	Other specified infantile cerebral palsy
343.9	Infantile cerebral palsy unspecified
351.8	Hemifacial spasms
378.00 through 378.9	Disorders of eye movement (strabismus)
478.75	Laryngeal spasm
530.0	Achalasia and cardiospasm
565.0	Anal fissure
705.21	Primary focal hyperhidrosis due to axillary
705.22	Gustatory hyperhydrosis (Frey's Syndrome)
723.5	Torticollis unspecified

b. Botulinum Toxin Type B

333.83	Spasmodic Torticollis

C. Procedure Code(s)

a. HCPCS Procedure Codes

J0585	Botulinum toxin type A, per unit
J0587	Botulinum toxin type B, per 100 units

b. CPT Codes for Botulinum Toxin Type A

31513	31571	64613	64640	67345

31570	64612	64614	64650	

c. CPT Codes for Botulinum Toxin Type B

64613

D. Coding Guidelines

a. Botulinum Toxin Type A (Botox)

The following CPT procedure codes are to be reported with the respective listed covered ICD-9-CM diagnosis codes when billing for botulinum toxin type A (Botox):

Procedure Code	Description	ICD-9-CM Diagnosis Code	Description
31513	Laryngoscopy, indirect; with vocal cord injection	478.75	Laryngeal spasm
31570	Laryngoscopy, direct, with injection into vocal cord(s), therapeutic	478.75	Laryngeal spasm
31571	Laryngoscopy, direct, with injection into vocal cord(s), therapeutic; with operating microscope or telescope	478.75	Laryngeal spasm
64612	Chemodenervation of muscle(s); muscle(s) innervated by facial nerve (e.g., for blepharospasm, hemifacial spasm)	333.81	Blepharospasm
		351.8	Hemifacial spasm nerve
64613	Chemodenervation of muscle(s) neck muscle(s) (e.g., for spasmodic torticollis)	333.83	Spasmodic torticollis
64614	Chemodenervation of muscles); extremity(s) and/or trunk muscle(s) (e.g., for dystonia, cerebral palsy, multiple sclerosis)	334.1	Hereditary spastic paraplegia
		340	Multiple sclerosis
		341.0 through 341.9	Other demyelinating diseases of central nervous system
		342.11	Spastic hemiplegia (dominant)
		342.12	Spastic hemiplegia (non-dominant)
		343.0 through 343.9	Infantile cerebral palsy
		530.0	Achalasia and cardiospasm

Procedure Code	Description	ICD-9-CM Diagnosis Code	Description
		705.21	Primary focal hyperhidrosis
64640	Destruction by neurolytic agent; other peripheral nerve or branch	565.0	Anal fissure
		705.21	Primary focal hyperhidrosis
64650	Chemodenervation of eccrine glands; both axillae	705.21	Primary focal hyperhidrosis
67345	Chemodenervation of extraocular muscle	378.00 through 378.90	Strabismus

b. Electromyography (EMG) Injections

Only one EMG per injection site may be reported. The following procedure codes for EMG guidance may be billed if appropriate:

Procedure Code	Description
92265	Needle oculoelectromyography, one or more extraocular muscles, one or both eyes, with interpretation and report
95860	Needle electromyography, one extremity with or without related paraspinal areas
95861	Needle electromyography, two extremities with or without related paraspinal areas
95867	Needle electromyography, cranial nerve supplied muscle(s), unilateral
95868	Needle electromyography, cranial nerve supplied muscles, bilateral
95869	Needle electromyography, thoracic paraspinal muscles (excluding T1 or T12)
95870	Needle electromyography, limited study of muscles in one extremity or non-limb (axial) muscles (unilateral or bilateral), other than thoracic paraspinal, cranial nerve supplied muscles, or sphincters
95873	Electrical stimulation for guidance in conjunction with chemodenervation
95874	Needle electromyography for guidance in conjunction with chemodenervation

c. Botulinum Toxin Type B (Myobloc)

The following procedure codes are to be reported with the corresponding ICD-9-CM diagnosis codes when billing for botulinum toxin type B (Myobloc).

Procedure Code	Description	ICD-9-CM Diagnosis Code	Description
64613	Chemodenervation of muscle(s) neck muscle(s) (e.g., for spasmodic torticollis)	333.83	Spasmodic torticollis

E. Modifiers

Providers are required to follow applicable modifier guidelines.

F. Billing Units

1. Botulinum Toxin Type A: 1 billing unit = 1 unit
2. Botulinum Toxin Type B: 1 billing unit = 100 units

G. Place of Service

Outpatient office settings.

H. Co-payments

Medicaid recipients aged 21 and older may be subject to co-payments for office visits.

I. Reimbursement

Providers must bill usual and customary charges.